Press Release

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WLF Comments on HHS Agency's Modernization of Safe Harbors from Anti-kickback Prosecutions

(*In re: HHS Office of Inspector General Anti-kickback Safe Harbors*)

> **"OIG has taken a positive step forward to bringing 'value-based care' to federal healthcare programs, but the agency's unfounded decision to exclude entire industries from new safe harbors threatens the proposal's viability."**
> —Glenn G. Lammi, WLF Chief Counsel, Legal Studies Division

WASHINGTON, DC—Washington Legal Foundation (WLF) has urged a federal healthcare regulator to reverse its decision to exclude pharmaceutical and medical-device manufacturers from the protection of proposed Anti-Kickback Statute safe harbors. In formal comments filed with the Department of Health and Human Service's Office of Inspector General's (OIG) on December 31, 2019, WLF applauds the agency's removal of regulatory barriers to care coordination and value-based care, but also expresses serious reservations with the proposed rule's discrimination against certain key players in federal healthcare programs.

The private healthcare market is rapidly moving away from pricing, contracting, and other arrangements based on the volume of services or products offered and toward arrangements based on tangible results. Such value-based arrangements can more closely align health outcomes with costs. HHS has encouraged greater use of outcome-based arrangements in Medicare and Medicaid, but because regulators would likely view compensation based on achieved outcomes, rebates, and other aspects of value-based care as unlawful kickbacks, federal healthcare contractors have refrained from such arrangements. In its October 17, 2019 proposal, OIG proposed safe harbors that will protect "value-based enterprise participants" from Anti-kickback Statute liability.

OIG also proposes that certain types of business entities, including producers of pharmaceuticals and durable medical devices, be prohibited from the protection of value-based-care safe harbors. The proposal further casts doubt on OIG's intention to define "traditional" medical-device manufacturers as value-based enterprise participants in the final rule. WLF argues that the justifications OIG cites for excluding all companies in the disfavored industries are unfounded and that the agency should move away from entity-based participation decisions when finalizing the proposal.

Celebrating its 43rd year, WLF is America's premier public-interest law firm and policy center advocating for free-market principles, limited government, individual liberty, and the rule of law.

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